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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WASHINGTON

JEREMY OLSEN,

Plaintiff,

v.

XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health and Human Services,

Defendant

No. 2:21-cv-00326-SMJ

MOTION FOR SUMMARY JUDGMENT AND PERMANENT INJUNCTION

Noting Date: August 5, 2022
Without Oral Argument

Pursuant to FED.R.CIV.P. 56, Plaintiff Jeremy Olsen moves for summary judgment of the underlying claims and for entry of a permanent injunction.

Before addressing the merits, Plaintiff notes that this is an unusual case in multiple respects. This Court's prior determination of "bad faith" represented only the 11th time in the last 10 years that the United States was held to have acted in "bad faith" as to both the underlying position by the Secretary and litigation conduct by his representative. Given the United States participation in more than 200,000 cases/year, the Secretary's conduct and this Court's finding were unusual. Incredibly, *after* this Court's finding, the Secretary continued to reject Mr. Olsen's claims (as well as the claims of thousands of others) on the same "bad faith" grounds. By Plaintiff's estimate, the Secretary's bad faith conduct is responsible for the deaths of thousands of American citizens. Importantly, the Secretary has never disputed that his bad faith conduct resulted in death.

Of course, that was the result of an illegal act (issuing CMS 1682-R without notice and comment in violation of the laws passed by Congress and signed by the President). Given the Secretary's demonstrated lack of integrity and trustworthiness as well as the absence of any dispute that the Secretary acted unlawfully, this Court should grant Olsen's motion for

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summary judgment and issue an injunction barring the Secretary from repeating the conduct that killed so many.

I. Background

A. The Notice and Comment Provisions of the Medicare Act

Pursuant to 42 U.S.C. § 1395hh(a)(2):

> No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).

As further provided in § 1395hh(b)(1):

> Except as provided in paragraph (2),[1] before issuing any regulation under subsection (a), the Secretary shall provide for notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon.

In *Azar v. Alina Health Services*, 139 S.Ct. 1804 (2019), the Supreme Court confirmed that the Medicare specific notice and comment provisions of 42 U.S.C. § 1395hh applied to Medicare rather than the notice and comment provisions of the Administrative Procedure Act.

[1] Containing exclusions not relevant here.

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B. CMS' Rulings and CMS 1682-R

In the period prior to January 12, 2017, numerous ALJs had found CGMs met the regulatory requirements of 42 C.F.R. § 414.202 and were covered were "durable medical equipment." [2]

CMS Ruling 1682-R issued on January 12, 2017, and became effective that same day. *See* AR450 ("EFFECTIVE DATE: This Ruling is effective January 12, 2017. Dated: January 12, 2017. /s Patrick Conway, MD"). Prior to January 12, 2017 (or at any time thereafter), CMS Ruling 1682-R was not published in the FEDERAL REGISTER. *See* Dkt. #1 at ¶ 19; Dkt. #41 at ¶ 19. Pursuant to 42 C.F.R. § 405.1063(b), CMS Rulings "are binding on all CMS components, [and[on all HHS components that adjudicate matters under the jurisdiction of CMS." *See also* 42 C.F.R. § 401.108(c). CMS 1682-R describes CMS rulings as "precedent final opinions and orders and statements of policy and interpretation." *See* AR435. CMS 1682-R "articulates CMS policy concerning the classification

[2] A listing of over 60 such decisions can be found at https://dparrishlaw.com/parrish-law-offices-wins-significant-victory-for-cgm-users/

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of continuous glucose monitoring system as durable medical equipment." *Id*.

As set forth there, CMS 1682-R establishes two categories of CGMs – "therapeutic" and "non-therapeutic." "Therapeutic" CGMs are alleged to meet the regulatory requirement of "primarily and customarily used to serve a medical purpose" and are covered. AR441-3. In order to qualify as a "therapeutic" CGM, CMS 1682-R required CGMs to "replace" home blood glucose monitors. AR449. CMS 1682-R further established the category of "non-therapeutic" CGMs which are alleged to be "adjunctive" / "precautionary" (non-statutory/non-regulatory terms) and not meet the regulatory requirement of "primarily and customarily used to serve a medical purpose" and are not covered. AR441-4.

Also on January 12, 2017, without notice and comment, Local Coverage Article (LCA) A52464 was amended to incorporate the new requirements of CMS 1682-R. *See* AR451-83. LCAs provide codes used for billing purposes. As set forth there:

> Effective for claims with dates of service on or after January 12, 2017, Medicare covers therapeutic CGM devices under the DME benefit. CGM devices covered by Medicare are defined in CMS Ruling 1682R as therapeutic CGM. CGM devices that do not meet the definition of a therapeutic CGM as defined in CMS Ruling 1682R will be denied as non-covered (no benefit).
>
> * * *

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> Codes A9276 (SENSOR; INVASIVE (E.G., SUBCUTANEOUS), DISPOSABLE, FOR USE WITH INTERSTITIAL CONTINUOUS GLUCOSE MONITORING SYSTEM, ONE UNIT = 1 DAY SUPPLY) and A9277 (TRANSMITTER; EXTERNAL, FOR USE WITH INTERSTITIAL CONTINUOUS GLUCOSE MONITORING SYSTEM) describe the supplies used with a non-therapeutic CGM. Codes A9276 and A9277 are not used to bill for supplies used with code K0554.
> Code A9278 (RECEIVER (MONITOR); EXTERNAL, FOR USE WITH INTERSTITIAL CONTINUOUS GLUCOSE MONITORING SYSTEM) describes any CGM system that fails to meet the DME Benefit requirements as described in CMS Ruling 1682R.

Thus, pursuant to the LCA, anything coded A9276, A9277, or A9278 is alleged to not meet the definition of "therapeutic" set forth in CMS 1682-R and is not covered.

C. Mr. Olsen's Claims in this Case

This case concerns two claims for CGM' sensor coverage submitted by Mr. Olsen.

1. ALJ Appeal no. 3-8946502107/M-20-1269

For the period April 19 – July 18, 2019, Mr. Olsen received a 90-day supply of sensors for use with his CGM. Mr. Olsen's claim was rejected initially, on redetermination, on reconsideration, by an ALJ (AR82-86), and by the MAC (AR3-12) all on the "bad faith" grounds that a CGM is not "primarily and customarily used to serve a medical purpose" as articulated in CMS 1682-R. The MAC decision issued on October 22, 2021,

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approximately six months after this Court found that position to constitute "bad faith" in *Olsen I*.

2. ALJ Appeal No. 3-10205345873

On March 10, 2021, Mr. Olsen received a 90-day supply of sensors for use with his CGM. Mr. Olsen's claim was rejected initially, on redetermination, on reconsideration, and by an ALJ (AR385-90) all on the "bad faith" grounds that a CGM is not "primarily and customarily used to serve a medical purpose" as articulated in CMS 1682-R.

II. DISCUSSION

A. CMS 1682-R Issued Illegally and Is Invalid

As set forth above, pursuant to 42 U.S.C. § 1395hh(a)(2), "[n]o rule, requirement of other statement of policy" that establishes or changes a standard concerning the scope of benefits, payment for services, etc., shall take effect unless promulgated by regulation issued in accordance with the notice and comment provisions. On its face, MCS 1682-R describes itself, inter alai, as a "statement[] of policy and interpretation." AR431.

Further, of course, by setting forth the standard of "precautionary" and "therapeutic" CGMs, CMS 1682-R purports to establish or change the standard concerning the scope of benefits, payment for services, or eligibility of individuals receiving a CGM. Thus, under § 1395hh, CMS

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1682-R cannot "take effect unless it is promulgated by the Secretary by regulations" (including compliance with the notice and comment provisions). *See* 42 U.S.C. § 1395hh.

Here, there is no genuine issue of material fact that the Secretary did not comply with the notice and comment provisions. Nothing was published in the Federal Register concerning proposed regulations, there was no opportunity for the public to comment, and there was no publication of final regulations. *See* 42 U.S.C. § 1395hh(b). Instead, in defiance of the statute, the Secretary simply issued a ruling establishing a new standard for benefits and, relying on that illegal standard, proceeded to reject claims (including Mr. Olsen's) on that basis. *See* AR11("The CMS Ruling, however, is binding on the Council and on ALJs, and we not decline to apply it on the basis the beneficiary advances."). Thus, the illegal ruling was used to deny tens of thousands of CGM claims resulting in deaths. Because the Secretary failed to comply with § 1395hh, CMS 1682-R issued illegally and, pursuant to 5 U.S.C. § 706(2), should be set aside and its enforcement enjoined.

B. The Denials in this Case Should Be Reversed

As set forth above, all the denials in this case are premised on the illegally issued CMS 1682-R. Thus, because that Ruling issued illegally,

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the denials based on it was also improper. Accordingly, the denials in this case should be reversed.

III. CONCLUSION

For the reasons set forth above, the CMS 1682-R issued illegally, this Court should set it aside and enjoin its enforcement, and reverse the denials in this case.

Respectfully submitted June 16, 2022.

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CERTIFICATE OF SERVICE

I hereby certify under penalty of perjury under the laws of the state of Washington that on the date below, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to all counsel of record.

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DATED June 16, 2022, at Seattle, Washington.

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